NATIONAL COMMISSION ON CHILDREN AND DISASTERS
SUBCOMMITTEE ON PEDIATRIC MEDICAL CARE

STATEMENT OF PURPOSE

The Subcommittee on Pediatric Medical Care will explore ways to improve the current system for providing acute medical care to children in disasters, including improvements to the current processes for developing, stockpiling, and distributing medical countermeasures for children in a disaster, and ensuring an effective emergency medical response system for children, with sufficient pediatric-specific surge capacity.

MEDICAL COUNTERMEASURES

Medical countermeasures refer to drugs, biological products, or devices that treat, identify, or prevent harm due to chemical, biological, radiological and nuclear agents. Children have unique physical characteristics that must be considered when developing medical countermeasures.

As a result, given their smaller physical size relative to adults, dosing of countermeasures can be challenging. Careful consideration of children's needs must be given when developing, stockpiling, and administering medical countermeasures. In particular, certain federal entities, such as the Biomedical Advanced Research and Development Authority (BARDA), have authority to implement changes in policy relative to countermeasures, and may therefore be central in responding to many of the concerns raised above relative to specific countermeasures for children.

In 2006, Congress passed the Pandemic and All-Hazards Preparedness Act, which provided authority for a number of programs related to the development and acquisition of medical countermeasures. Chief among these was the later establishment of BARDA, within the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS), to direct and coordinate the countermeasure efforts. The activities of BARDA build upon the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) that was established by HHS in 2006. PHEMCE is a coordinated, inter-agency effort to bring about the development and purchase of necessary vaccines, drugs, therapies and diagnostic tools for public health emergencies. BARDA now directs the PHEMCE, by coordinating its activities, as well as working with other federal departments/agencies. Some of the responsibilities of these two entities include coordinating research, development, and procurement of emergency medical countermeasures; and setting deployment and use strategies for the countermeasures held in the Strategic National Stockpile, which is a stockpile of large quantities of medicines and supplies for use in the event of a public health emergency. Any policies designed to address the unique concerns of children's countermeasures will likely fall within the authority of BARDA.

Once developed, potential medical countermeasures must be approved by the FDA through a process designed to demonstrate that they are safe and effective for their intended uses. The process begins with animal testing to check for toxicity, followed by three phases of human clinical trials designed to determine the safety, proper dosage, side effects, and effectiveness of the countermeasure for a particular indication. The clinical trials are typically sponsored/funded by a company hoping to market the new drug. Clinical trial participants must not be placed at an unreasonable risk for harm, and must give their informed consent. This process can cost upwards of $800 million. BARDA will help supply funding for top priority countermeasure programs where funding from private sources is unavailable or insufficient. Although countermeasure programs in general have been given priority under BARDA, separate priority may need to be given to developing children's countermeasures, due to their unique physiology.

A number of rules and guidelines specifically address the use of children as research subjects in clinical trials for vaccines and other medical products. An FDA Ethics Working Group Consensus Statement was released on April 19, 2000, which stated that pediatric studies should be conducted on subjects who may benefit from participation in a trial, and preference should be given to children who actually assent to participation (as opposed to mere permission granted by a parent or guardian). This echoes rules set forth in the Code of Federal Regulations regarding protections for children involved as subjects in research. HHS will only conduct or fund research involving children who do not receive immediately benefit if the research "presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children," and only after consultation with a panel of experts and an opportunity for public review and comment has occurred. Any efforts to use children as clinical participants in the development of medical countermeasures must therefore pass these regulatory hurdles, although it is possible that an agent released in a terrorist attack or disaster could be considered a serious problem affecting the health or welfare of children. It is important to note that certain countermeasures have already been approved for children, including ciprofloxacin to treat anthrax, potassium iodide tablets ("Thyro-Safe") as a treatment for exposure to radioactive iodine, and Atropen as a treatment for exposure to nerve gas.

- *Potential Issues/Policy Ideas*
  - Statutory and/or regulatory recommendations to facilitate the development and pre-authorization of medical countermeasures for pediatric use
    - Expansion of the Emergency Use Authorization (EUA) procedure
    - Development of a consensus driven countermeasure approval process
  - Training of medical professionals, school officials and parents to properly administer medical countermeasures to children.
  - Strategies to increase funding for development, stockpiling, and distribution of pediatric-appropriate medicines and supplies

- Development of non-medical countermeasures to protect children in the event of a pandemic

➢ *Adjustment of the Emergency Use Authorization (EUA) procedures*

Children are known to be at *greater* risk of: 1) exposure to community-dispersed chemical, biological, radiological and nuclear terrorist agents, 2) absorption of comparable doses of these agents, and 3) mortality and morbidity from comparable doses of the agents that are absorbed. Yet, there are several agents for which medical counter-measures are available for use in adults and included in the Strategic National Stockpile (SNS), but for which comparable agents for use in children have not yet been approved by the FDA, and therefore missing from the SNS.

For example, autoinjectors for adults exposed to nerve agents are a component of CHEMPACKS, a forward deployed component of the SNS. Yet, autoinjectors for use in children are not yet approved or available in the United States, despite strong advocacy efforts on the part of the pediatric medical community for at least 6 years. Of note, autoinjectors for nerve agents have long been approved for use in Israel and available in that country. As a result, children, our most vulnerable population to the effects of potential terrorist agents, are not yet adequately protected in the United States – they are *less* protected than in some other countries and *less* protected than adults in our own country, even though they are at greater risk.

Preliminary Recommendations:

The Commission recommends a change to the Emergency Use Authorization process that will permit, in the absence of FDA-approved counter-measures for use in children, the determination by a panel of medical experts (in consultation with the CDC, NIH, and FDA) that the risk-benefit ratio based *on currently available data* justifies the use of specific counter-measure agents in the scenario of a *potential threat* of a biological, chemical, nuclear, or radiologic agent.

The Commission recommends that funding should be secured in the amount required to ensure equitable purchase of counter-measures for the Strategic National Stockpile and other caches of counter-measures (e.g., CHEMPACKS, a forward deployed component of the SNS) as shall be deemed necessary that are appropriate for use in children to *at least* the extent that children are at risk and represent a vulnerable portion of the population. (see Proposed Expansion of the Emergency Use Authorization for Pediatric Medical Counter-measures Draft)

ACUTE MEDICAL CARE FOR CHILDREN

In order to properly analyze the extent of a child's injuries after a disaster, the proper medical response knowledge regarding emergency pediatric treatment is necessary. Unfortunately, the majority of pre-hospital and hospital-based emergency care providers do not have enough regular exposure to pediatric emergencies to acquire and maintain the necessary skills to provide acute medical care for children in disaster situations.

Furthermore, our nation's emergency care system is already over-burdened, fragmented, and under-funded and these problems are multiplied in the case of disasters. When it comes to meeting the medical needs of children, the emergency care system is particularly limited: there are not enough medical personnel skilled in pediatric medical care or continuing education programs for providers to maintain their skills, there is a lack of regional and national protocols for pediatric preparedness and emergency care, and there is a dearth of pediatric-specific equipment and pharmaceuticals.

There have been no lack of recommendations aimed at addressing gaps in pediatric emergency medical services, yet action has been limited and not uniform.

In considering the creation of pediatric acute medical care training standards and inclusion of pediatric expertise in response plans and on Disaster Medical Assistance Teams, the subcommittee might consider the following questions:

- Would you recommend national protocols/guidelines for pediatric readiness and continuing education and/or state and regional protocols?
    - If regional/state protocols, how would you ensure uniformity and that they are kept up to date?
- How can you standardize pediatric treatment, reduce regional differences, and ensure that remote areas have access to pediatric training and facilities?
- How would you integrate pediatric preparedness into DMATs and NDMS?
- Can you discuss any potential mechanisms for improving the chronic under-funding of child-specific acute emergency care?
- What new policies are needed to ensure that medical response personnel are adequately trained to appropriately address the needs of children in disasters?
- Are specific funding streams required to provide for stockpiling of child-appropriate medical supplies?

    - *Potential Issues/Policy Ideas*

        - Advocating for incorporation of a dedicated pediatric representative into the DMAT structure
        - Assessing ways for emergency medical training to more systematically incorporate vital information about pediatric-specific emergency care issues

- Evaluating the NDMS to ascertain whether it appropriately addresses the needs of children in disasters, and subsequently advocating for appropriate policy changes

PRELIMINARY RECOMMENDATIONS

The Commission recommends that all federal agencies charged with potentially administering acute medical care to children in disasters implement standards of pediatric acute care training, maintain pediatric specific equipment in the cache' and require pediatric expertise on DMAT teams.

The Commission recommends that HHS work with existing pediatric organizations (American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions) to assure pediatric hospitals and clinicians are fully integrated into the national, state, regional and local response plans for children.

The Commission recognizes the important work of the DHHS Health Resources and Services Administration's Emergency Medical Services for Children program for improving capability for care of children during disasters and recommends its reauthorization and continued funding.